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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/692,634	10/19/2000	Paul John Rennie	8308	8314
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27752	7590	12/23/2005		
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CINCINNATI, OH 45224

EXAMINER
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SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

<b>Application No.</b> 09/692,634	<b>Applicant(s)</b> RENNIE ET AL.	
<b>Examiner</b> Shahnam Sharareh	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 12 October 2005.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-7 and 20-27 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-7 and 20-27 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_.

### DETAILED ACTION

1. Amendment filed on October 12, 2005 has been entered. Claims 1-7, 20-27 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the amendments. However, the new claims are subject to a new ground of rejection.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-5, 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li, J et al CN 1079259 in view of Yamamoto (English Abstract, Eisei Kagaku (1990), 36(4), 332-7).

Li et al teaches a nasal preparation for treating influenza or common comprising edible vinegar. (see abstract).

Yamamoto teaches that vinegar liquid comprise pyroglutamic acid and a secondary organic acid such as succinic or acetic acid which fall within the scope of the instantly claimed mono, di or tri carboxylic acids. Applicant is informed that pKa value is an inherent property of pyroglutamic acid. Accordingly, pyroglutamic acid of edible vinegar would have possessed a pKa value within the ranges of the instantly claimed pyroglutamic acid. Yamamoto fails to teach the methods of administering vinegar solution for treating cold or flu.

However, it would have been obvious to one of ordinary skill in the art at the time of invention to use edible vinegars nasally for treatment of cold or flu, because as taught

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by Li et al, edible vinegars are used in nasal formulations that treat cold or flu. Thus, the ordinary skill in the art would have had reasonable expectation of success in treating such condition with nasal formulations comprising edible vinegar solution.

Further, more absent a showing of criticality, it would have been obvious to one of ordinary skill in the art at the time of invention to use a suitable carrier system including homogenous liquid or ointment formulation and optimize the viscosity of such compositions for nasal delivery, because the pharmacological properties of vinegar is independent of its delivery carrier.

3. Claims 6-7, 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li, J et al CN 1079259 in view of Yamamoto as applied to claims 1-5, 20-25, and further in view Szentmiklosi et al US Patent 5,244,880

Their combined teachings fail to explicitly show the use of a mucoadhesive carbohydrate polymer.

Szentmiklosi discloses that suitable carrier systems for topical compositions can comprise carbohydrate polymers such as carbopol or carbohydrate polymer (see col 5, lines 20-40). Szentmiklosi's topical compositions comprise pyroglutamic acid, an organic acid, a mucoadhesive polymers and even propellants for aerosol delivery of topical formulations (examples 2-9). Szentmiklosi teaches that his aqueous solutions can be prepared conventionally in the form of oleaginous formulations such as ointments, creams, foams or emulsions (col 3, lines 37-41; col 2, lines 29-65; example 8). Further, Examiner takes the position that topical compositions encompass nasal composition, because they are all viewed in the art as topical methods of delivery.

Accordingly, absent a showing of unexpected result, it would have been obvious to one of ordinary skill in the art at the time of invention to employ a mucoadhesive polymer in aqueous solutions of Yamamoto, because as taught by Szentmiklosi, one of ordinary skill in the art would have had a reasonable expectation of success in preparing topical formulations that are specific for any intended site of delivery.

***Response to Arguments***

4. Applicant's arguments filed October 12, 2005 have been fully considered but they are not persuasive.
5. Applicant argues that none of the references explicitly or implicitly teach administration of pyroglutamic acid-based compositions into the nasal passage for treating colds or flu. (see Remarks at page 9). In response, Examiner states that Li such line of argument is not commensurate with the scope of the claims.

The instant methods are directed to methods of treating cold with a composition comprising pyroglutamic acid. Li clearly teaches methods of treating cold with a composition that contains vinegar solution. Yamamoto teaches that vinegar contains pyroglutamic acid. Therefore, Li's composition contains pyroglutamic acid and is used to treat flu or cold. Employing a suitable carrier system such as aerosolized spray is a matter of design choice and an obvious modification of a property that is already known in the art.

6. Applicant further argues that there is no motivations in the art to use the mucoadhesive polymers described in Szentmiklosi and combine them with the vinegar,

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because Szentmiklosi's formulations contain isopropanol which can not be used in nasal preparations. (see Remarks at page 9-10).

In reply, Examiner states that applicant's arguments are not commensurate with the scope of the claims because the instant claims do not exclude the use of isopropanol. Further, Szentmiklosi is used to show that pyroglutamic acid and mucoadhesive polymers are compatible in topical formulations. Szentmiklosi describes forming a topical composition that comprises pyroglutamic acid and a mucoadhesive polymer. Thus, Szentmiklosi suggests that mucoadhesives and pyroglutamic acids are compatible in aqueous topical formulations. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to use such teachings in the art and prepare a solution of vinegar that contains pyroglutamic acid, as suggested by Li and Yomamoto and then further add a mucoadhesive polymers to optimize its viscosity, because as suggested by Szentmiklosi, mucoadhesive polymers are compatible with pyroglutamic acid for topical uses.

### ***Conclusion***

7. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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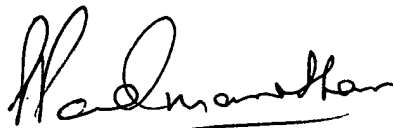
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SS

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER